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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,443

11/29/2005

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EXAMINER

DANG, PHONG SON H

ART UNIT

PAPER NUMBER

3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,443	ODERMATT ET AL.	
	Examiner	Art Unit	
	SON DANG	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/11/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed 09/24/2008 has been entered. Claims 1-28 remain pending in the application. Claims 29-30 have been added. The previous 112 USC rejections of claims 2-3, 6-10, 12-18, 20-24 and 27-28 are withdrawn in light of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 8-14, 16-21 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,328,259 to Anderson (Anderson) in view of US PG PUB No. 2005/0002893 to Goldmann (Goldmann).

In Reference to Claims 1-5, 8-15, 19-21 and 25-30:

Anderson teaches:

A planar implant (Fig. 1) comprising a planar support (6, Fig. 1) with two faces (upper and lower side of gauze, Fig. 1), at least one face of the support being provided with an absorbable adhesive layer (Film 5, Fig. 1) which is able to adhere to human or animal tissue (Col. 3, lines 20-21) (Fig. 1, col. 7, lines 58-61).

The adhesive layer is has anti-infective properties (Col. 3, lines 26-27).

The adhesive layer (Film 5, Fig. 1) at least partially covers, preferably completely covers, the at least one face of the support (Fig. 1, Col. 7, lines 58-61).

The adhesive layer (Film 5, Fig. 1) is designed to cover the planar support only around the edges and/or to protrude beyond the edges (Fig. 1, protrude upwardly) of the planar support.

The adhesive layer (Film 5, Fig. 1) is provided on both faces of the support (Col. 9, lines 47-48).

The adhesive layer (Film 5, Fig. 1) is designed as an open layer (Col. 9, lines 47-48) and is in particular absorbent (Col. 6, lines 32-34).

The adhesive layer (Film 5, Fig. 1) is hydrophilic and in particular is able to take up aqueous fluids by swelling (Col. 6, lines 32-34).

The adhesive layer (Film 5, Fig. 1) is present in the form of a nonwoven (Film 5, Fig. 1), in particular a three-dimensional nonwoven (The protective film 5 is "non woven" and "3-D").

The adhesive layer (Film 5, Fig. 1) is present in the form of an open-cell foam (Col. 6, lines 32-34).

The layer (Film 5, Fig. 1) is soluble in water (Col. 11, lines 1-8).

The layer (Film 5, Fig. 1) is a bioabsorbable polysaccharide (Col. 4, lines 44-45, starch is a polysaccharide).

The polysaccharide is one from the group comprising starch (Col. 4, lines 44-45).

The adhesive layer (Film 5, Fig. 1) has a structured surface (6, Fig. 1) on its outer face.

The planar support (6, Fig. 1) is porous and flexible (Col. 1, lines 19-20), and in particular is formed from a textile material (Col. 2, lines 21-22).

The textile support, is at least partially absorbable, in particular completely absorbable (Col. 3, lines 47-49).

The anti-adhesive layer contains polyvinyl alcohol and/or carboxymethylcellulose, and in particular consists of polyvinyl alcohol (Col. 4, lines 44-45).

It is designed as a patch (Figs. 1-2) which has the adhesive layer (5, Fig. 1) on at least one face.

It is present as a tube section which is designed for connection of tubular hollow organs (Col. 9, lines 55-57).

It is for an internal application in an organism (Col. 3, lines 46-49), in particular in the area of wounds.

The planar support being connected on both faces to an adhesive layer (Film 5, Gauze 6, Fig. 1) for apposition of vertical and horizontal tissue layers, the planar implant preferably being absorbable.

Anderson fails to teach:

One polymer which carries free aldehyde groups and whose aldehyde groups are able to react with nucleophilic groups of the tissue Claim 1.

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Polymer carrying aldehyde groups is a polyethelene glycol with at least three terminal aldehyde groups in Claims 16 and 17.

Polymer carrying aldehyde groups is partially cross-linked in Claim 18.

The proportion of glucose units oxidized to the aldehyde in the dextran polyaldehyde is at least 20% in Claim 15.

The proportion of glucose units oxidized to the aldehyde in the dextran polyaldehyde is 35 to 100% in Claim 29.

The proportion of glucose units oxidized to the aldehyde in the dextran polyaldehyde is 50-85% in Claim 30.

Goldmann teaches:

One polymer which carries free aldehyde groups and whose aldehyde groups are able to react with nucleophilic groups of the tissue (Details description).

Polymer carrying aldehyde groups is a polyethelene glycol with at least three terminal aldehyde groups (Details description)

Polymer carrying aldehyde groups is partially cross-linked (Details description).

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the material of Goldmann into Anderson as a design of choice as it would achieve an art-equivalent result. It would have been obvious to one of ordinary skill in the art at the time of the invention to employ other chemical compositions such

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as an oxidized/unoxidized polysaccharide to arrive with the final product such as starch that is known in the art for gluing tissues together.

It is also obvious to one of ordinary skill in the art to employ chemical composition cross-linked together for gluing biological tissue.

Even though Anderson did not teach the exact percentage of the proportion of glucose units oxidized to the aldehyde in the dextran polyaldehyde group to form more covalent bonds for adhesive to the body tissues, the claim is rejected because it is not support the patentability of subject matter encompassed by the prior art. It is not inventive to discover the optimum ranges by routine experimentation. (MPEP 2144.05 A)

4. Claims 6, 7, 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Goldmann and further in view of US Patent No. 6,319,264 to Tormala et al. (Tormala).

In Reference to Claims 6 and 7:

Anderson teaches:

The implant as claimed in claim 1 (see rejection of Claim 1 above), characterized in that the support (Gauze 6, Fig. 1) has an adhesive layer (Film 5, Fig. 1) on one face.

Anderson fails to disclose:

An anti-adhesive layer on the other face.

Tormala teaches:

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An anti-adhesive layer on the other face (2nd layer, Fig. 2) in order to prevent tissue adhesion (Col. 2, lines 7-10).

The anti-adhesive layer has a closed and in particular smooth surface (2nd layer, Fig. 2, Col. 4, lines 61-63).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the implant of Anderson with the anti-adhesive layer of Tormala to produce an implant that only one layer has the ability to adheres to the injured area and the other layer has the ability to prevent adhesion to other tissues as explicitly taught by Tormala.

In Reference to Claim 22:

Anderson teaches:

The implant as claimed in claim 1 (see rejection of Claim 1 above).

Anderson fails to teach:

One face of the support is provided with at least one anti-adhesive layer which is preferably absorbable.

Tormala teaches:

That one face of the support is provided with at least one anti- adhesive layer (2nd layer, Fig. 2) which is preferably absorbable (Col. 2, lines 35-38).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combine the implant of Anderson with the anti-adhesive layer which is absorbable of Tormala to produce an implant that could be use for internal bleeding.

In Reference to Claim 24:

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Anderson teaches:

The implant as claimed in claim 1 (see rejection of Claim 1 above).

Anderson fails to teach:

That it is designed as a hernia mesh having the adhesive layer on the face which is intended to bear on the abdominal wall, and in that the other face of the hernia mesh preferably has at least one layer which is designed as an anti-adhesive layer and prevents adhesion of body tissue to the mesh.

Tomala teaches:

An implant characterized in that it is designed as a hernia mesh (Col. 2, lines 35-36) having the adhesive layer on the face (1st layer, Fig. 2) which is intended to bear on the abdominal wall, and in that the other face of the hernia mesh preferably has at least one layer which is designed as an anti-adhesive layer (2nd layer, Fig. 2, Col. 2, lines 7-10) and prevents adhesion of body tissue to the mesh.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined the implant of Anderson with the anti-adhesive layer of Tomala to produce an implant that only one layer has the ability to adhere to the injured area and the other layer has the ability to prevent adhesion to other tissues as explicitly taught by Tomala.

Response to Arguments

5. Applicant's amendments have overcome the 112 (2nd paragraph) rejections from the previous Office Action.

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6. Applicant's arguments, see page 9, lines 7-8 and 11-12, filed 09/24/2008, with respect to the rejection(s) of claim(s) 1-5, 8-14, 19-21, 23 and 25-28 under 102 (b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of US PG PUB No. 2005/0002893 to Goldmann for Claims 1-5, 8-14, 19-21, 23 and 25-28. Claims 16-18 are also have a new ground(s) of rejection made in view Goldmann. Goldmann provides the remedy for the deficiency in Anderson by providing the polymer and the three aldehyde groups which are lack in Anderson's.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 7,179,660 to Kirakossian et al teaches a carriers coated with polysaccharides, their preparation and use.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SON DANG whose telephone number is (571)270-5809. The examiner can normally be reached on Monday-Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SD

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773